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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	I hereby certify that this paper is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on this date:
McMICHAEL et al.	
Serial No.: 09/495,186	
Filed: February 1, 2000	
For: TREATMENT OF SYMPTOMS OF ASTHMA, ALLERGIES AND OTITIS MEDIA	**July 7, 2003**
Group Art Unit: 1633	Jeffrey S. Sharp
Examiner: Michael C. Wilson	Registration No. 31,879 Attorney for Applicants

APPLICANTS' RESPONSE UNDER 37 C.F.R. §1.111

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This is in response to the Office Action dated July 3, 2001 in which the Notice of Allowance issued previously on December 1, 2001 has been withdrawn after payment of the issue fee on February 27, 2002. Specifically, all pending claims (15-19) stand rejected under 35 U.S.C. §112 (first and second paragraphs). Reconsideration and allowance of the claims is solicited in light of the following remarks. This response is timely filed as a petition for a three-months extension of time to July 15, 2003 is submitted herewith.

I. The Outstanding Rejections

Claims 15-19 stand rejected under 35 U.S.C. §112 (first paragraph) for lack of enablement.

Claims 15-20 (sic 19) stand rejected under 35 U.S.C. §112 (second paragraph) as being indefinite.

II. Patentability Arguments

A. The Lack of Enablement Rejections of Claims 15-19 Under 35 U.S.C. §112 (First Paragraph) Should Be Withdrawn.

The rejections of claims 15-19 under 35 U.S.C. §112 (first paragraph) for lack of enablement should be withdrawn because Applicant's invention is not an antibacterial method but is instead directed to treatment of the symptoms of otitis media.

Contrary to the assumption inherent in the rejection, the reduction of bacteria counts does not necessarily correlate with otitis media symptoms. While otitis media is frequently secondary to infection, the elimination or treatment of infection is not necessarily sufficient or effective to treat the symptoms of otitis media. In fact, the symptoms of otitis media are thought to be the consequence of an inflammatory response to infection which inflammatory response is not relieved when the infection is eliminated. (See Exhibit A attached hereto in which "otitis media" is defined as "acute or chronic inflammation of the middle ear.")

For this reason, whether the administration of DNA to a subject reduces bacteria count is irrelevant to the issue of whether the therapy effectively treats pain or other symptoms of otitis media. Thus, the Examiner has failed to present any evidence or logic that casts doubt on the efficacy of the treatment claimed by Applicant and described in Examples XX through XXIX of the specification. Accordingly, the rejections of claims 1-7 under 35 U.S.C. §112 (first paragraph) should be withdrawn.

B. The Rejections of Claims 15-19 Under 35 U.S.C. §112 (Second Paragraph) Should Be Withdrawn.

The rejection of claims 15-19 under 35 U.S.C. §112 (second paragraph) as being indefinite should be withdrawn as the language "so as to not effect gene transfer" is clear and understandable to those of skill in the art in light of the teachings of the specification. The invention relates to the administration of DNA for the treatment of symptoms of otitis media but does not perform this method by transfection or otherwise by the practice of gene expression or gene therapy. In this context it is clear that "gene transfer" does not relate to transferring DNA from the bottle to the patient.

It was in the course of prosecution of a related case in which clarification was sought by the Patent Office Examiner of whether the mechanism of action through which DNA administration performed its function was by gene therapy effected by gene transfer. In

response to that inquiry the claim language in that application was amended to recite that the DNA was administered in a manner "so as to not effect gene transfer" in great-grandparent application U.S. Serial No. 08/755,092 which issued as U.S. Patent No. 5,726,160. Moreover, each of, 6,096,721, 5,955,442, 5,726,160, and parent patent 6,100,244 comprise this identical language in their claims. For the foregoing reasons, the rejection under 35 U.S.C. §112 (second paragraph) should be withdrawn.

CONCLUSION

For all of the foregoing reasons, the rejections should now be withdrawn and allowance of all pending claims 15-19 is respectfully solicited. Should the Examiner wish to discuss any issues of form or substance in order to expedite allowance of the pending application, he is invited to contact the undersigned attorney at the number indicated below.

Respectfully submitted,

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By: _____
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July 7, 2003